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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



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Applicant's or agent's file reference HL-20132-PCT		FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. <b>PCT/KR2003/001850</b>	International filing date (day/month/year) <b>08 SEPTEMBER 2003 (08.09.2003)</b>	Priority date (day/month/year) 11 SEPTEMBER 2002 (11.09.2002)	
International Patent Classification (IPC) or national classification and IPC  <b>IPC7 C07D 211/90</b>			
Applicant  <b>HANLIM PHARMACEUTICAL CO., LTD. et al</b>			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the report
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  <b>09 MARCH 2004 (09.03.2004)</b>	Date of completion of this report  09 DECEMBER 2004 (09.12.2004)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer  KIM, Hee Jin  Telephone No. 82-42-481-5412 

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2003/001850

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement) under Article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets \_\_\_\_\_

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	2-5, 7, 8	YES
	Claims	1, 6, 9	NO
Inventive step (IS)	Claims		YES
	Claims	2-5, 7, 8	NO
Industrial applicability (IA)	Claims	1-9	YES
	Claims		NO

### 2. Citations and explanations (Rule 70.7)

The following documents have been considered for the purpose of this report:

D1 : CN 1343663 A

D2 : US 6291490 B1

#### 1. Novelty and Inventive Step

##### (1) Claims 1,6,9

The present invention relates to a nicotinic acid salt of S-amlopidine, a process for preparing the same and a pharmaceutical composition comprising the same as an active ingredient.

However, D1 discloses amlodipine nicotinate, a pharmaceutical composition thereof and a process for preparation (see page 3, table 1 and example 5 in D1) thereof. Therefore, the subject matter of claims 1, 6 and 9 does not possess novelty over D1.

##### (2) Claims 2-5

Claims 2-5, which are dependent on claim 1, limit the form of solvate of amlodipine nicotinate as an anhydrous form, a hydrous form and a dihydrate form. None of the prior art does not mention the specific form of solvate of amlodipine nicotinate. Therefore, the subject matter of claims 2-5 is considered to be novel.

However, the diversification of the sorts of the solvate is conventional technique in this field because another solvate form can be easily prepared by changing the solvent if required. Accordingly, claims 2-5 do not involve an inventive step.

##### (3) Claims 7 and 8

Also, none of the prior art discloses the process for preparing amlodipine nicotinate comprising a recrystallization step or drying a hydrous form of the salt to obtain an anhydrous form. Therefore, the subject matter of claims 7 and 8 is considered to be novel.

(Continued on Supplemental Sheet.)

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## Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

### Continuation of:

However, it is well known to a person skilled in the art to recrystallize using methanol and isopropanol (or water and isopropanol) and to prepare the anhydrous form by drying a hydrous form as describes in D2. Therefore, the subject matter of claims 7 and 8 do not involve an inventive step.

### 2. Industrial applicability

The present invention appears to be industrially applicable.